

# **Program Announcement**

**Department of Defense Congressionally Directed Medical Research Programs**

**Bone Marrow Failure Research Program**

**Resource Development Award**

**Funding Opportunity Number: W81XWH-11-BMFRP-RDA**

**Catalog of Federal Domestic Assistance Number: 12.420**

## **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-application Submission Deadline:** 5:00 p.m. Eastern time (ET), June 21, 2011
- **Invitation to Submit an Application:** July 2011
- **Application Submission Deadline:** 11:59 p.m. ET, September 14, 2011
- **Scientific Peer Review:** November 2011
- **Programmatic Review:** February 2012

*New for fiscal year 2011 (FY11): The Grants.gov Research & Related Budget form is a mandatory component of all Grants.gov application packages.*

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## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Description

The Bone Marrow Failure Research Program (BMFRP) was established in Fiscal Year 2008 (FY08) to promote innovative research focused on bone marrow failure (BMF). Appropriations for the BMFRP from FY08 through FY10 totaled \$9.75 million (M). The FY11 appropriation is \$4M.

The vision of the BMFRP is to understand and cure BMF disease. Toward that end, the program challenges the scientific community to design innovative research that will advance the understanding of inherited and acquired BMF diseases to improve the health and life of individuals living with these diseases, with the ultimate goals of prevention and/or cure.

**FY11 BMFRP Objectives:** The objectives of the BMFRP are to fund scientifically meritorious research focused on BMF syndromes and their long-term sequelae. Studies that primarily focus on myeloproliferative neoplasms, leukemia, or other malignancies are discouraged. However, studies investigating BMF syndromes and their progression to other malignancies, such as leukemia, are acceptable. Proposals involving therapeutics, including but not limited to bone marrow transplantation, are strongly encouraged to address issues unique to BMF syndromes.

### B. Award Information

The BMFRP recognizes the critical need for improved research resources to advance the field of BMF research. Therefore, the Resource Development Award, a product-driven award mechanism, supports the development of much needed research resources for use by the Principal Investigator's (PI's) laboratory and the BMF research community at large to promote basic research on BMF.

The following are significant features of this award mechanism:

- 1. Research Resource(s):** Filling critical gaps in the research resource needs of the BMF scientific community with tangible products is the objective of this award mechanism. Examples of resources may include, but are not limited to, autoimmune animal models, centralized databases made available for data mining of published information, and animal model-specific therapeutics. The proposed research resource should present a clear advantage when compared to currently available resources.
- 2. Resource Distribution:** The PI and organization must agree to make the final research resource available to the scientific community for reasonable administrative costs (e.g., costs required for packaging and shipping the resource). The Government intends to publicize the availability of and the contact information for obtaining the research resource on the Congressionally Directed Medical Research Programs website.

***Inclusion of preliminary data is not required.*** Although preliminary data are not required, Resource Development Award applications should be based on a sound scientific rationale that is established through logical reasoning and/or a critical review and analysis of the literature.

***Use of human subjects and human anatomical substances is limited.*** Research projects involving human subjects or human anatomical substances will not be supported unless they are exempt under Title 32, Code of Federal Regulations, Part 219, Section 101(b)(32 CFR 219.101[b]) or eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110). In brief, exempt studies may include, but are not limited to, research on normal educational practices, special cases of educational tests and/or surveys, or the collection of existing data, documents, records, or pathological specimens in a de-identified method. Exemption is first determined by the local Institutional Review Board (IRB) of record. Investigators must review their institutional requirements and guidelines for filing with the IRB for exempt status. Studies that do not qualify for exempt status or for expedited review will be administratively withdrawn and will not be funded. Additional information may be found on the US Army Medical Research and Materiel Command (USAMRMC) Human Research Protection Office website (<https://mrmc.amedd.army.mil/rodorphrpo.asp>).

### **C. Eligibility Information**

- Investigators at or above the level of an Assistant Professor (or equivalent) are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

### **D. Funding**

- The maximum period of performance is **3** years.
- The maximum allowable direct costs for the entire period of performance is **\$225,000** plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget form. In addition, for this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Salary
- Research Supplies
- Research related subject costs
- Equipment

- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings

*The Office of the Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately \$1M of the \$4M FY11 BMFRP appropriation to fund approximately 3 Resource Development Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.*

## **II. SUBMISSION INFORMATION**

Submission is a multi-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (<https://cdmrp.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

Submission of the same research project to different funding opportunities within the same program and fiscal year is discouraged. The Government reserves the right to reject duplicative applications.

### **A. Where to Obtain the Application Package**

To obtain the complete application package, including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number: W81XWH-11-BMFRP-RDA.

### **B. Pre-Application Submission Content and Form**

All pre-application components must be submitted by the PI through the CDMRP eReceipt system (<https://cdmrp.org/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs and organizations identified in the application should be the same as those identified in the pre-application. The PI should not change after the pre-application deadline. If a change in PI or organization is necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at [help@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt system by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
- **Collaborators and Conflicts of Interest (COI) – Tab 3**

- **Required Files – Tab 4**

**Preproposal Narrative (one-page limit):** The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons.

The Preproposal Narrative should include the following:

- **Resource(s):** Describe the final research resource(s) that will be developed and the critical gap in the research needs of the BMF scientific community that it fills. Explain the potential impact of the proposed research resource(s) and how the project will, if successful, move the BMF research field forward.
- **Rationale:** Clearly articulate the rationale for the proposed project by presenting the ideas and reasoning behind the developing the resource(s).
- **Development:** State the project’s objective(s) and specific aims.

**Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application are limited to:

- **References Cited (one-page limit):** List the references cited (including URLs if available) in the preproposal narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **Key Personnel Biographical Sketches (four-page limit per individual):** Include biographical sketches for the PI and other key collaborators.

- **Submit Pre-application – Tab 5**

- **Other Documents Tab**

No additional documents are required.

### **Pre-Application Screening**

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the DOD and CDMRP, pre-applications will be screened based on the following criteria:

- **Adherence to the intent of the award mechanism**
- **Research Resource(s)**
  - The degree to which the proposed research resource(s) fills a gap in the research needs of the BMF scientific community.
  - How the proposed research resource(s) will, if successfully developed, impact the field of BMF research.

- **Principal Investigator and Research Team**

- Whether the PI meets the eligibility requirements.
- To what degree the PI and research teams' backgrounds and BMF-related expertise are appropriate to successfully develop the proposed research resource(s).

- **Notification of Pre-Application Screening Results**

Following the pre-application screening, PIs will be notified of whether or not they are invited to submit an application; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. Pre-application notification dates are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

### **C. Application Submission Content and Form**

*Applications will not be accepted unless the PI has received a letter of invitation.*

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative (AOR) through the Grants.gov portal (<http://www.grants.gov/>).

**Grants.gov application package components:** For the Resource Development Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

**1. SF 424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

**2. Attachments Form**

- **Attachment 1: Project Narrative (six-page limit):** Upload as "ProjectNarrative.pdf."

Describe the proposed project in detail using the outline below.

- **Research Resource(s):** Describe the research resource(s) to be developed and the critical gap in the research needs of the BMF scientific community that it fills.
- **Background:** Present the ideas and reasoning behind the proposed resource development project.
- **Specific Aims:** Concisely explain the project's specific aims to be funded by this award.
- **Resource(s) Development Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls and statistical plan, in

sufficient detail for evaluation. Address potential problem areas and present alternative methods and approaches.

- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. *Each component has no page limit unless otherwise noted.*
  - References Cited : List the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
  - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
  - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project, and any additional facilities or equipment proposed for acquisition at no cost to the USAMRMC. Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present contract under which the facilities or equipment items are now accountable. There is no form for this information.
  - Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then they must be included. Extra items will not be reviewed.
  - Letters of Organizational Support: Provide a letter (or letters if applicable), signed by the Department Chair or appropriate organization official, reflecting the laboratory space, equipment, and other resources available for the project.
  - Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.” Describe the proposed resource(s) development project including the following elements: the research resource(s) and the need of the BMF scientific community that is addressed, background, study design and the potential impact of the anticipated research resource(s). Describe how the resource(s) will be made available to the research community.
- **Attachment 4: Public Abstract (one-page limit):** Upload as “PublicAbs.pdf.” Include an overview of the proposed resource(s) development project that can be readily understood by lay persons. Clearly describe the resource(s), the critical need that it will address, and how it will be made available to the research



community. Discuss the impact that the resource(s) might have on the field of BMF research and/or patient care. Do not duplicate the technical abstract.

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information.

- **Attachment 6: Impact Statement (one-page limit):** Upload as “Impact.pdf.”

Describe why the proposed research resource(s) is important to research designed to study the causes and progression of BMF, and/or improvements in patient care and/or quality of life.

***Describe the short-term impact:*** Detail the anticipated research resource(s) that will be directly attributed to the results of the proposed project.

***Describe the long-term impact:*** Describe the anticipated long-term gains from the development of the proposed research resource(s), and compare these to BMF research resources currently available, if applicable.

- **Attachment 7: Research Resource(s) Sharing Plan (one-page limit):** Upload as “DatShar.pdf.”

Clearly articulate the commitment of the PI to making the proposed BMF research resource(s) available to the scientific community. Describe how the resource(s) will be distributed to investigators as requested.

**3. Research & Related Senior/Key Person Profile (Expanded) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

- PI Biographical Sketch (four-page limit): Upload as “Biosketch\_LastName.pdf.”
- PI Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
- Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch\_LastName.pdf.”
- Key Personnel Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”

**4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.

- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”

**5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

**6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

## **D. Submission Dates and Times**

All submission dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines shall result in application rejection.

## **E. Other Submission Requirements**

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Organizations are required to provide a Data Universal Number System (DUNS) number and register with the Central Contractor Registry (CCR) to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

## **III. APPLICATION REVIEW INFORMATION**

### **A. Application Review and Selection Process**

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General, USAMRMC, based on technical merit, the relevance to the mission of the DOD and CDMRP, and the specific intent of the award mechanism. The highest scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

## B. Application Review Criteria

1. **Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

- **Impact**
  - The degree to which the proposed research resource(s) is important to research designed to study the causes and progression of BMF, and/or improvements in patient care and/or quality of life.
  - How well the anticipated short-term outcome(s)/product(s) (intellectual and/or tangible) are described.
  - How well the anticipated long-term gains from this research course are described and compared to information/products currently available, if applicable.
- **Research Resource(s):**
  - The degree to which the proposed research resource(s) fills a gap in the research needs of the BMF scientific community.
  - Whether the PI plans to share the research resource(s) with the scientific community.
  - Whether the resource sharing plan is feasible.
- **Resource(s) Development Strategy and Feasibility**
  - How the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature, BMF-relevant preliminary data, or logical reasoning.
  - How well the objectives, specific aims, experimental design, methods, and analyses are developed and integrated into the project.
  - How well the PI identifies potential problems and addresses alternative approaches.
  - Whether the proposal includes an appropriate statistical plan with power analysis, if applicable.

In addition, the following unscored criteria will also contribute to the overall evaluation of the application:

- **Personnel**
  - How the research team's background and BMF-related expertise are appropriate to accomplish the proposed work.
  - To what degree the levels of effort are appropriate for successful conduct of the proposed work.

- **Environment**
    - How the scientific environment is appropriate for the proposed research.
    - How the research requirements are supported by the availability of and accessibility to facilities and resources (including collaborative arrangements).
    - How the quality and extent of institutional support are appropriate for the proposed research.
  - **Budget**
    - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
  - **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application components influenced the review.
2. **Programmatic Review:** To determine the application's relevance to the mission of the DOD and CDMRP, as well as to make funding recommendations, the following equally considered criteria are used by programmatic reviewers:
- Adherence to the intent of the award mechanism
  - Program portfolio composition
  - Programmatic relevance
  - Ratings and evaluations of the peer reviewers
  - Relative impact

### **C. Recipient Qualification**

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

### **D. Application Review Dates**

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

### **E. Notification of Application Review Results**

Each PI and organization will receive notification of the funding recommendation. PIs will receive a scientific peer review summary statement on the strengths and weaknesses of the application.

## **IV. ADMINISTRATIVE ACTIONS**

After receipt of pre-applications from CDMRP eReceipt or applications from Grants.gov, the following administrative actions may occur:

### **A. Rejection**

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative exceeds page limit. Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of an application for which a letter of invitation was not received.

### **B. Modification**

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative and Preproposal Narrative.
- Documents not requested will be removed.
- Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

### **C. Withdrawal**

The following may result in administrative withdrawal of the pre-application or application:

- FY11 BMFRP Integration Panel (IP) member is found to be involved in the preapplication or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY11 BMFRP IP members may be found at <http://cdmrp.army.mil/bmfrp/panels/panel11>.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the Research and Related Budget form exceed the maximum allowed by this Program Announcement/Funding Opportunity.

- Inclusion of URLs with the exception of links to published references.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- The PI does not meet the eligibility criteria.
- The proposed research project does not qualify for exempt status under Title 32, Code of Federal Regulations, Part 219, Section 101(b) (32 CFR 219.101[b]) or is not eligible for expedited review (32 CFR 219.110 or 21 CFR 56.110).

#### **D. Withhold**

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

### **V. AWARD ADMINISTRATION INFORMATION**

#### **A. Award Notice**

Awards will be made no later than September 30, 2012. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

#### **B. Administrative and National Policy Requirements**

Refer to the General Application Instructions, Appendix 4, Section C, for general information regarding administrative and national policy requirements.

#### **C. Reporting**

Refer to the General Application Instructions, Appendix 4, Section D, for general information on reporting requirements.

#### **D. Award Transfers**

Refer to the General Application Instructions, Appendix 4, Section E, for general information on organization or PI changes.

## **VI. AGENCY CONTACTS**

### **A. CDMRP Help Desk**

Questions related to Program Announcement/Funding Opportunity content or submission requirements and questions related to the submission of the pre-application through the CDMRP eReceipt System should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 1-301-682-5507

Email: [help@cdmrp.org](mailto:help@cdmrp.org)

### **B. Grants.gov Contact Center**

Questions related to application submission through the Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 1-800-518-4726

Email: [support@grants.gov](mailto:support@grants.gov)

***Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.***

## VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
	Upload Public Abstract (PublicAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Impact Statement (Impact.pdf) as Attachment 6.	
	Upload Research Resource(s) Sharing Plan (DatShar.pdf ) as Attachment 7.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete form as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	